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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,808	02/19/2002	Manas Kumar Majumdar	08702.0086-00000	7146

22852 7590 01/09/2006

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EXAMINER	
WOODWARD, CHERIE M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/078,808	MAJUMDAR ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,23-29 and 31-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23-29 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Amendment of 24 October 2005, is acknowledged and entered. Claims 21, 23-29, and 31-37 are pending and under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Response to Arguments

Claim Objections/Rejections Withdrawn

2. The rejection of claims 21, 23-29, and 31-37 under 35 U.S.C. 102(a) as being anticipated by WO 00/29552 is withdrawn pursuant to the 131 declaration of Majumdar and Morris.

Claim Objections/Rejections Maintained

Claim Rejections - 35 USC § 112

3. The rejection of claims 23, 24, 28-29, 32-33, 35, and 36, under 35 U.S.C. 1 12, first paragraph, scope of enablement, is maintained for the reasons set forth in the Office Action of 22 June 2005. The specification, while enabling for the use of BMP-2, BMP-9, and other BMPs known to have effects on cartilage, does not reasonably provide enablement for all bone or cartilage inducing factors or all BMPs, as broadly claimed. Applicant's arguments filed 25 October 2005 have been fully considered but they are not persuasive.

The instant claims recite a method for inducing chondrogenesis comprising administering an effective amount of composition comprising CD105+ (endoglin-positive) cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. The claims further recite a method of treating arthritis comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. Also claimed is a method for treating articular cartilage defects or damage comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, a method for repairing cartilage tissue comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow, a suitable matrix carrier, and a factor selected from bone inducing factors and/or cartilage

inducing factors, wherein the factor is a BMP, further comprising administering a bone and/or cartilage inducing factor, wherein the factor is a BMP.

Applicants argue that the claims are directed to a method for inducing chondrogenesis by administering a composition comprising CD105+ cells (specifically, claim 21). Applicants state that the specification discloses that the compositions administered in the methods of the invention may further comprise bone and/or cartilage inducing factors to the CD105+ cells (see, e.g., specification at page 6, lines 14-17). Applicants also state that the specification discloses that preferred bone and/or cartilage inducing factors include the transforming growth factor-beta (TGF-β) superfamily of proteins, bone morphogenetic proteins (BMPs), and growth differentiation factors (GDFS) (specification at page 6, line 22-24) and specifically identifies a large number of known bone and/or cartlage inducing factors (specification at page 6, line 19 to page 7, line 23). Applicants' arguments have been considered, but are not persuasive.

The assertion that all members of the TGF-β superfamily may be used in combination with the administration of CD 105+ cells cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities. For example, Vukicevic *et al.* (1996, PNAS USA 93:9021-9026), disclose that OP-1, a member of the TGF-β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-β family members BMP-2 and TGF-β1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging columns 1-2). See also, for example, Massague, who reviews other members of the TGF-β family (1987, Cell 49:437-8, esp. p. 438, column 1, second full paragraph to the end). Similarly, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity of naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). The differences between PDGF and VEGF are also seen *in vivo*, wherein endothelial-pericyte associations in the eye are disrupted by intraocular administration of PDGF but accelerated by intraocular administration of VEGF (see, for example, Benjamin et al., 1998, Development 125:1591-1598; Abstract and pp. 1594-1596).

Therefore, based on the discussions above concerning the specific examples of structurally similar proteins that have different functions, along with the art's recognition that one cannot rely upon structural similarity alone to determine functionality, the specification fails to teach the skilled artisan

how to use all members of the TGF-β superfamily, all BMPs, and/or GDFs in the claimed invention without resorting to undue experimentation.

Due to the large quantity of experimentation necessary to determine all members of the TGF-β superfamily, all BMPs, and/or GDFs, the lack of direction/guidance presented in the specification regarding same, the absence working examples directed to same, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, and the breadth of the claims which fail to recite particular biological activities and also embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The rejection of claims 23, 24, 28-29, 32-33, 35, and 36, under 35 U.S.C. 1 12, first paragraph, scope of enablement, is maintained for the reasons set forth in the Office Action of 22 June 2005 and as stated supra.

4. The rejection of claims 23, 24, 28-29, 32-33, 35, and 36 under 35 U.S.C. 1 12, first paragraph, written description, is maintained for the reasons set forth in the Office Action of 22 June 2005. Applicant has not described the characteristics of the bone and cartilage inducing factors, or of the members of the BMP family, that would be useful for inducing chondrogenesis and thus also for treating arthritis or injury. The structural and functional features required for the desired activity are not provided. Applicant's arguments filed 25 October 2005 have been fully considered but they are not persuasive.

The instant claims recite a method for inducing chondrogenesis comprising administering an effective amount of composition comprising CD105+ (endoglin-positive) cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. The claims further recite a method of treating arthritis comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. Also claimed is a method for treating articular cartilage defects or damage comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, a method for repairing cartilage tissue comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow, a suitable matrix carrier, and a factor selected from bone inducing factors and/or cartilage inducing factors, wherein the factor is a BMP, further comprising administering a bone and/or cartilage inducing factor, wherein the factor is a BMP.

Applicant's aruge that they are not relying on the identification of a molecule as a BMP to describe the recited genus. Rather, Applicants are relying on the known bone and cadilage inducing activities of a number of members of the TGF-β superfamily and on the functional claim limitation of the term "bone and cartilage inducing factors." This description and the claim limitation clearly define the scope of the claims to the population of proteins that have bone and cadilage inducing activity. Moreover, Applicants specifically identify families of factors (TGF, BMP, GDF, etc) that are generally defined by common structural features (page 6, line 19 to page 7, line 23 of the specification). In addition, Applicants describe a significant number of individual species of the bone and/or cadilage inducing factors to support the recited genus. As in Capon, where the structural features of known DNA segments did not need to be further described, additional descriptions of the structures of bone and cartilage inducing factors are not necessary because both their structures and their functions are well known in the art. The bone and/or cartilage inducing nature of these proteins are easily assessable by well-known methods, such as the Rosen-Modified Sampath Reddi rat bone formation assay, as disclosed in, e.g., U.S. Patent No. 5,013,649, which is incorporated by reference into the specification. Fudhermore, even if, as the Examiner asserts, BMP-12 and BMP-13 do not have the claimed bone and cartilage inducing activity, they are then not encompassed by the claims and thus do not need to be better described. The skilled artisan could readily determine whether a particular factor possesses bone and/or cartilage inducing activity. Applicants' arguments have been considered, but are not persuasive.

Vas-Cath Inc. Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., TGF-β superfamily and on the functional claim limitation of the term "bone and cartilage inducing factors.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the*

University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

There is are two species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.BMP-2 and BMP-9*. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. Applicants' argument that the recitation of the TGF-β superfamily and the functional claim limitation of the term "bone and cartilage inducing factors is sufficient to provide an adequate description of all of the potential variants with the requisite alternative activity. However, Applicant has not adequately described all possible TGF-β superfamily members that are bone and cartilage inducing factors. As noted *supra*, the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities.

There is substantial variability among the species. In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The rejection of claims 23, 24, 28-29, 32-33, 35, and 36 under 35 U.S.C. 1 12, first paragraph, written description, is maintained for the reasons set forth in the Office Action of 22 June 2005 and *supra*.

New Grounds of Rejection

Claim Rejections - 35 USC § 102(e)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 21, 23-24, 26-28, 32-33, and 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldberg *et al.*, (US 2002/0110544, issued as U.S. Patent 6,835,377, claiming priority to May 13, 1998, hereinafter '377 patent).

The instant claims recite a method for inducing chondrogenesis comprising administering an effective amount of composition comprising CD105+ (endoglin-positive) cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. The claims further recite a method of treating arthritis comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. Also claimed is a method for treating articular cartilage defects or damage comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, a method for repairing cartilage tissue comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow, a suitable matrix carrier, and a factor selected from bone inducing factors and/or cartilage inducing factors, wherein the factor is a BMP, further comprising administering a bone and/or cartilage inducing factor, wherein the factor is a BMP.

The '377 patent claims a method for regenerating articular cartilage by administering cultured human mesenchymal stem cells with a chondrogenesis promoting factor in a biomatrix, wherein the cartilage defect comprises articular cartilage injury or loss of cartilage in a joint. The '377 patent also claims a method for treating a cartilage defect resulting from osteoarthritis comprising administering human mesenchymal stem cells to a host in need thereof. Further, the '377 patent teaches BMPs as molecules known to be involved with chondrogenesis (column 9, lines 55-58).

Thus, the '377 patent anticipates instant claims 21, 23-24, 26-28, 32-33, and 35-36 as anticipating methods of inducing chondrogenesis, treating arthritis, treating articular cartilage defects or damage, and repairing cartilage tissue, comprising administering an effective amount of composition comprising CD105+ (endoglin-positive) cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP. Further, the '377 patent anticipates instant claims 21, 23-24, 26-28, 32-33, and 35-36 being the same invention as claims 1-2, 4, 8, 9, 11-12, 15-16, and 18 of the '377 patent.

7. Claims 21, 23-29, and 31-37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,761,887 (Kavalkovich *et al*, PCT Pub WO 00/29552, hereinafter referred to as the '887 patent). The '887 patent teaches an alginate layer system formed by seeding mesenchymal stem cells (MSCS) in alginate. These MSCS are known in the art to express CD105 (endoglin); see also, for example, Barry *et al*., Biochem. Biophys. Res. Comm. 1999, vol. 26541), pp. 134-139; previously cited in the Office Actions of 26 September 2003) The '887 patent teaches that alginate constructs can be formed using non-cultured populations of MSCS (p. 10,lines 10- 19) and that the constructs can be used for cartilage regeneration (p. 5, lines 26-28). The '887 patent further teaches that BMP-2 can be included as a chondrogenic agent (p. 8, lines 21-24). The '887 patent thus anticipates method of administering compositions comprising non-expanded CD 105+ cells to regenerate cartilage, and additionally anticipates methods of administering such cells in combination with a matrix and/or with a BMP.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 21, 23-29, and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg *et al.*, (US 2002/0110544, issued as U.S. Patent 6,835,377, claiming priority to May 13, 1998, hereinafter '377 patent), as stated *supra*, in view of Barbara *et al.*, (JBC 8 January 1999 274(2):584-594).

The instant claims recite a method for inducing chondrogenesis comprising administering an effective amount of composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP, wherein the BMP is BMP-2 or BMP-9. The claims further recite a method of treating arthritis comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, further comprising administering a bone and/or cartilage inducing factor, wherein said factor is a BMP, wherein the BMP is BMP-2 or BMP-9. Also claimed is a method for treating articular cartilage defects or damage comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow and a suitable matrix carrier, a method for repairing cartilage tissue comprising administering an effective amount of a composition comprising CD105+ cells isolated from bone marrow, a suitable matrix carrier, and a factor selected from bone inducing factors and/or cartilage inducing factors, wherein the factor is a BMP, wherein the BMP is BMP-2 or BMP-9.

As stated *supra*, the '377 patent claims a method for regenerating articular cartilage by administering cultured human mesenchymal stem cells with a chondrogenesis promoting factor in a biomatrix, wherein the cartilage defect comprises articular cartilage injury or loss of cartilage in a joint. The '377 patent also claims a method for treating a cartilage defect resulting from osteoarthritis comprising administering human mesenchymal stem cells to a host in need thereof. Further, the '377 patent teaches BMPs (column 9, lines 55-58). The '377 patent does not teach BMP-2 or BMP-9.

BMP-2 binding of endoglin (CD 105) is taught by Barbara *et al.*, (see p. 584, abstract, p. 585, column 1, paragraph 2). Additionally, Barbara *et al.*, teach that endoglin (CD 105) is not a true receptor, but rather, is an accessory protein that interacts with the ligand binding receptors of multiple members of the TGF-β superfamily (p. 591, column 2, first paragraph). Further, Barbara *et al.*, teach that BMP-2's association with endoglin is more transient than endoglin's association with other proteins (p. 591, second column, last paragraph, to p. 592, first column, first paragraph).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of the '377 patent with the teachings of Barbara *et al.*, to include BMP-2 as a factor that would induce chondrogenesis because BMP-2, a well-known member of the TGF-β superfamily, known to be involved in chondrogenesis, has been shown to interact with endoglin (CD

105). The person of ordinary skill in the art would have been motivated to make those modifications because the BMP-2 is part of a multifunctional set of growth and differentiation factors known to control biological processes such as embryogenesis, organogenesis, morphogenesis of tissues like bone and cartilage, wound repair, and hematopoiesis. The skilled artisan would have been motivated to include BMP-2 in a method for inducing chondrogenesis, treating arthritis, treating articular cartilage defects or damage, and repairing cartilage tissue because BMP-2 has been shown to interact with endoglin (CD 105) in a specific, but transient manner, thus permitting regulated chondrogenesis.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

NO CLAIM IS ALLOWED.

Due to the new grounds of rejection herein, this action is made nonfinal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMW

Brenda Brumback

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